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APPLICATION GUIDE FOR MEDICAL ELECTRICAL EQUIPMENT

PART 1 GENERAL REQUIREMENTS AND ELECTRICAL INSTALLATIONS

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APPLICATION GUIDE FOR MEDICAL ELECTRICAL EQUIPMENT

PART 1 GENERAL REQUIREMENTS AND ELECTRICAL INSTALLATIONS

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APPLICATION GUIDE FOR MEDICAL ELECTRICAL EQUIPMENT

PART 1 GENERAL REQUIREMENTS AND ELECTRICAL INSTALLATION

0. FOREWORD

0.1 This Indian Standard (Part 1) was adopted by the Indian Standards Institution on 30 July 1985, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 The application of medical electrical equipment, and the number of medical procedures employing such equipment have grown considerably during the last years. Many accidents related to the application of medical electrical equipment have been reported, the figure of unreported cases may be even higher.

0.3 Apart from improper selection of equipment, most of these accidents result from wrong application, bad maintenance faults, and electrical installation.

0.4 This application guide deals mainly with the safe application of medical equipment in non-mobile hospitals or medically used rooms, when both the equipment and the installation conform to relevant Indian Standards.

0.5 This standard applies to measures for providing and maintaining safety and is divided into two parts.

Part 1 General requirements and electrical installation, and

Part 2 Safety provisions, application, operation and maintenance.

0.6 This standard is based on IEC Draft document 62A (Secretariat) 68 Draft — General guidelines for the safe application medical electrical equipment (technical application code).

1. SCOPE

1.1 This standard (Part 1) specifies general requirements for the safe application of electrical equipment used in medical practice and the requirements for electrical installation.

2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions, in addition to those given in IS : 1885 (Part 43)-1977*, shall apply.

2.1 Accompanying Documents — Documents accompanying equipment or an accessory thereof, containing all important information for the operator, and installer or assembler of equipment, particularly regarding safety.

NOTE — Accompanying documents are considered to be part of the respective equipment.

2.2 Category MP1 — Procedures in which intentionally the patient is not in contact with medical electrical equipment.

NOTE — To be performed with Type B, Type BF or Type CF equipment.

2.3 Category MP2 — Procedures in which intentionally or non-intentionally the patient is in conductive contact with medical electrical equipment (excluding those procedures mentioned in MP3).

NOTE — To be performed with Type B, Type BF or Type CF equipment.

2.4 Category MP3 — Procedures with direct cardiac application, that is, Type CF equipment only.

NOTE — To be performed with Type B, Type BF or Type CF equipment.

2.5 Class I Equipment — Equipment intended for connection to an external supply in which accessible conductive parts which may give rise to electric shock in the event of a fault occurring in the basic safety insulation of live parts connected to an external supply are provided with means to connect them to a protective earth conductor in the fixed wiring of the installation.

2.6 Class II Equipment — Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

Electrotechnical vocabulary : Part 43 Electrical equipment used in medical practice.

a) Class II equipment may have parts operating at medical safety extra-low voltage.

b) Class II equipment may have an enclosure made of insulating material of accessible conductive material or of a combination of these.

c) In certain special cases, such as the signal terminals of electrical equipment, safety impedance may be used in Class II equipment if these technique can be included without detriment to the safety level.

d) Class II equipment may only be provided with means for connection to earth for functional (as distinct from protective) purposes.

e) Metal-encased Class II equipment may be provided with means for the connection of a potential equalization conductor to the enclosure.

2.7 Combination of Equipment — Several pieces of equipment which are interconnected to achieve a desired function.

2.8 Direct Cardiac Application — The use of equipment which may come in direct conductive connection to the patient's heart.

2.9 Electrical Installation — The assembly of all wiring, switches, transformers, and other parts intended to provide facilities for supply, protection against electric shock or other necessary functions in medical practice. Excluded are permanently or non-permanently connected medical electrical and other electrical equipment.

2.10 Instructions for Use — Part of the accompanying documents containing the information necessary for the correct application, operation, and maintenance of the equipment, and for understanding its operation.

2.11 Internal Electrical Power Source — Power source incorporated in the equipment intended to provide the electrical power necessary for its function.

2.12 Intensive Care Room — Room in which bed patients are monitored independently of an operation by means of electromedical equipment. Body actions may be stimulated, if required.

2.13 Medical Electrical Equipment — Electrical equipment, composed of one or more items, including any interconnecting means and provided with not more than one connection to the supply mains, specified for medical use.

2.14 Medically Used Rooms — Rooms intended to be used for medical, dental or veterinary examination, treatment or monitoring of a person or animal, shall also apply to Doctors' Dentists' and Veterinary Surgeons' rooms.

2.15 Operator — Person utilizing equipment.

2.16 Patient Environment — Any area up to 1·5 m distance from the intended location of the patient in which intentional or unintentional contact between patient and equipment or some other person touching the equipment can occur.

2.17 Touch Voltage — Voltage appearing, during an insulation fault, between simultaneously accessible parts.

2.18 Technical Description — Part of the accompanying documents providing data and characteristics of medical electrical equipment (or an indication where they may be found) insofar as they may be considered to be essential for operation, maintenance, and repair.

2.19 Type B Equipment — Class I or II equipment or equipment with an internally power source providing an increased degree of protection against electric shock particularly regarding:

a) allowable leakage currents, and

b) reliability of the protective earth connection (if present).

2.20 Catheter — A flexible tube for admitting or removing gases or liquids through channels of the body.

2.21 Type CF Equipment — Class I or II equipment or internally powered equipment, providing a high degree of protection against electric shock particularly regarding allowable leakage currents, and having an F-type isolated (floating) applied part.

NOTE — Type CF equipment is primarily intended for direct cardiac application.

3. NATURE OF HAZARDS

3.1 Electrical equipment used in medical practice may expose patient, operator and surroundings to a number of hazards of the following nature:

a) Energies delivered to the patient or user in normal use;

b) Energies delivered to the patient or user in single fault condition;

c) Absence of function in life-supporting equipment;

d) Absence of function or interruption of non-repeatable examinations or treatments; and

e) Human errors during operation of equipment.

Energies delivered may be of an electrical nature (including radiation and accelerated atomic particals) of a mechanical nature, of a thermal nature (temperatures and fire) or of a chemical nature. High frequency interference may be a hazard if it leads to false signals or disturbance of automatic processes.

3.2 Some of the hazards specified in **3.1** are, of course, also present in electrical equipment other than that used in medical practice. However, safety in connection with the use of electrical equipment used in medical practice shall be considered keeping in mind the following particular aspects :

a) The inability of the patient or the user to detect the presence of certain potential hazards, such as ionizing radiation or high frequency radiation;

b) Absence of normal reactions of the patient (ill, unconscious, anaesthetized, fastened to table, etc);

c) Absence of normal protection to currents provided by the normal skin if it is penetrated or treated especially to obtain a low skin-resistance;

d) Support or replacement of vital body functions may depend on the reliability of equipment;

e) Combination of high-power equipment and sensitive low-signal equipment, often in ad-hoc combinations;

f) Application of electrical circuits directly to the human body, either through contacts to the skin or through insertion of probes into internal organs;

g) Environmental conditions, particularly in operating theatres, which may present a combination of humidity, moisture and/or fire or explosion hazards caused by anaesthetic media and cleaning agents; and

h) Simultaneous connection to the patient of more than one piece of mains-operated equipment.

3.3 These hazards may be caused by :

1) electrical energies in many forms, either as electrical current passing through the human body or in converted form a radiation, ultrasonic or high frequency energy or accelerated elementary particles;

2) incorrect administration of a substance;

3) mechanical forces introduced by moving heavy equipment, improper use, improper functioning due to electrical or mechanical breakdowns, the absence of protective measures, the presence of dangerous surfaces, corners or edges, instability, expelled parts and the like;

4) mains frequency and high frequency interference which may affect automatic processes, registration of diagnostic data or treatment;

5) excessive temperatures on accessible surfaces which might lead to burns or fright-reactions;

6) fire if equipment defects lead to deposition of molten material, burning insulation and the like outside the enclosure;

7) chemical hazards by the emission of chemically agressice, poisonous or hot liquids or gases or contact with biologically unsafe materials;

8) human errors lead to hazards in several forms, for example:

   a) faulty use of equipment, for example, wrong sequence of switches, so that in some cases an inappropriate potential may be applied to the patient. This can be avoided to some extent by inbuilt safety features in the equipment and adequate instructions of the operator. Cancelling an alarm rather than correcting the fault which triggers it is dangerous.

   b) transducers may be misplaced. This can damage the patient directly, but may also lead to a wrong diagnosis or inappropriate therapy which in itself may precipitate fatality.

   c) draft in calibration of a monitoring system in misleading if not detected and corrected. Some of the more sophisticated pieces of equipment now include an error code readout to draw attention to common faults which may cause hazards.

   d) in life support systems, interchanging connections may lead to suffocation and death.

   e) fire hazards if the equipment is used in an explosive atmosphere without proper care.

9) component breakdown in life-supporting equipment;

10) breakdown of the power supply or other environmental calamities; and

11) parts of equipment which may become contaminated and are not easily cleaned may be a potent source of cross infection, particularly in debilitated patients.

12) Hazards due to electrostatic discharges.

3.4 Burns may occur when thermal energy is supplied to a part of the body faster than it may be removed. Because the body responds to cold by skin vasoconstriction to prevent further heat loss, burns can occur more readily in cold patients blood, whether in a transfusion system or if the patient is particularly susceptible to overheating, the red cells lysing, and the proteins being denatured (hard boiled eggs) above 41°C but even lower temperatures can be dangerous in certain circumstances. Special techniques are advisable in warning hypothermic patients to prevent heat injury.

3.5 The continuity of a patient's life may depend upon the functioning of equipment. In such a case even the reliability of the equipment and installation becomes a safety factor.

3.6 In a number of cases the repeated exposure of the physician who may diagnose or treat many patients a day may be the primary reason for concern.

3.7 The human being has a limited capability to absorb energies appearing in whatever form. Exceeding these limits, which have been established by experience and research, may cause injury or death. Lately a tread is developing to protect the human being even against harmless but unpleasant experiences which could be avoided without affecting the intent of the treatment.

4. ELECTRIC STOCK AND FIBRILLATION

4.1 Electric shock occurs when the body or part of it forms a pathway for discharge or flow of electricity. Alternating current at about 50 or 60 Hz provides the most risk of death from ventricular fibrillation. For currents passing through intact skin, for 1 second, 1 mA is the threshold of sensation 10 mA or more one cannot let go 50 mA or more pain and mechanical injury 100 mA or more ventricular fibrillation.

4.1.1 At higher current such as 6A or more, a sustained cardiac contraction may occur and may be followed by normal cardiac rhythm when the current flow ceases; current density may produce severe burns.

4.2 Current density is critical in determining the degree of damage. Current density at the heart is critical in the production of fatal ventricular fibrillation. Depending on the points of entry and exit of current, more or less current may pass through the heart. For example, a current of 200 mA passing from hand to hand has the same effect on the heart as 80 mA passing from front of chest to left hand. The heart is particularly susceptible during the early venticular repolarization phase; if the duration of current exceeds one cardiac cycle than the likelihood of ventricular fibrillation is markedly increased. If an insulated conductor, such as a pacemaker lead, or a catheter makes contact directly with the heart muscle, the current density will be such that currents as low as 40 μA in this conductor may introduce ventricular fibrillation.

4.3 Where such a direct cardiac contact is made, permissible leakage currents in all equipment in the area with which the patient sight come in contact directly or indirectly, must be below these levels.

5. GENERAL SAFETY CONSIDERATIONS

5.1 Consideration of relevant factors and a careful study of existing standards and literature lead to the fact that safety of medical electrical equipment cannot be ensured by the safety requirements in the equipment alone, but also by a combination of measures in the equipments the electrical installation and their maintenance, proper choice of equipment, and safe application.

5.2 The most important factors are:

a) safety of the equipment,

b) safety of the electrical installation, and

c) safe and correct application, which depends upon :

  1) availability and readability of accompanying documents,

  2) operatcrs knowledge of safety characteristics of equipment, and

  3) an effective maintenance scheme.

6. ELECTRICAL INSTALLATIONS IN MEDICALLY USED ROOMS INCORPORATING SAFETY MEASURES AND TESTING AFTER INSTALLATIONS

6.1 General Requirements

6.1.1 Electrical installations in medically used rooms shall conform to National Electrical Code.

6.1.2 As such, some parts of the installation may be present in the patient's environment where potential differences, that could lead to excessive currents through the patient, must be avoided. For this purpose a combination of earthing of equipment and potential equalization in the installation seems to provide the best solution. A disadvantage of such a system is that in the case of an insulation fault in circuits directly connected to supply mains, the fault current may cause a considerable voltage drop over the protective earth conductor of the relevant circuit. Since a reduction of such a voltage drop by the application of increased cross-sectional areas of protective conductors is usually impractical, available solutions are the reduction of the duration of fault currents to earth by special devices or the application of a power supply which is isolated from earth.

6.2 Supply System

6.2.1 Generally a power supply system including a separated protective conductor is required, (TN-S-System).

6.2.2 It is recommended that the electrical installations for use in hospitals should be a five-conductor system with separated neutral and protective earth conductors. The supply system's neutral point is generally directly earthed.

This system provides a combination of earthing of equipment and potential equalization and thus preventing potential differences between both equipment and extraneous conductive parts in the patient environment. Under normal conditions, currents harmful to the patient caused by these potential differences are avoided. For this reason, no system using a combined neutral and protective earth conductor on erection of new electrical installations shall be used.

6.3 Additional Safety Provisions

6.3.1 Depending on the nature of the examinations or treatments performed, additional provisions to the protective earth conductor in medically used room are made to increase the safety and reliability of the supply mains, for example :

a) Supplementray equipotential bonding to minimize the effects of touch voltages;

b) Residual current protective devices to minimize the effects of touch voltages;

c) Isolated supply systems to minimize leakage currents and to prevent disconnection from the mains supply in case of insulation faults in equipment; and

d) Emergency power supplies to maintain the function of equipment in case of interruption of the normal mains supply.

6.4 Floating Neutral — In electrical installations, when the neutral point is left floating and no neutral conductor is used, the fault current by isolation breakdown is normally reduced to a low level.

6.5 Other Safety Factors — The use of extension cords and multiple adaptors shall be avoided; care shall be taken that enough socket outlets are installed. All measures shall be taken to prevent explosion and fire hazards and accidental discontinuity of power supply.

6.6 P1 Medical TN-S System

6.6.1 Example is shown in Fig. 1.

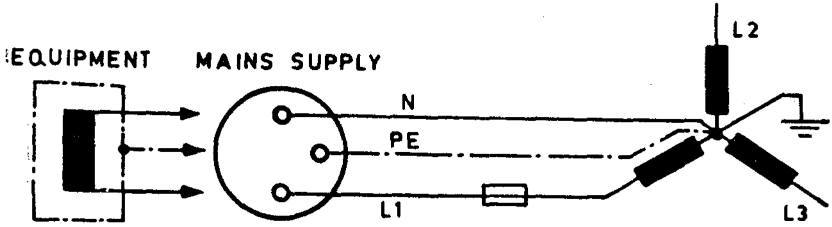


FIG. 1 MEDICAL TN-S SYSTEM

6.6.2 *Protective Measure* — All accessible conductive parts of Class I equipment are conductively connected to the protective earth conductor. Consequently, disconnection from the mains is affected by overcurrent protecting device in the installation, the insulation between the mains and the accessible conductive parts fails.

6.6.3 *Restriction* — Due to earth fault currents (for example, leakage currents) appearing in or outside the medically used rooms and flowing through the protective earth conductor care should be taken of impermissible touch voltage between accessible conductive parts of the equipment and extraneous conductive parts (waterpipes, central heating).

NOTE — In order to improve the limited safety properties of this system for medically used rooms, combinations with additional safety measures as shown below can be used:

a) with P2 : supplementary equipotential bonding;

b) with P2 + P4; residual-current protective device added to P2; and

c) with P2 + P5; medical isolated transformer (IT) system added to P2.

6.6.4 *Initial Testing of the Room* — Checking shall be done to see that the leads connected to the protective conductor bar are designated, marked and destinated according to the drawings of the installation system.

The impedance of the protective earth conductors between protective earth busbar and each connected protective earth contact in wall socket outlets, shall not exceed 0·2 Ω.

The impedance of 0·2 Ω is sufficiently low only for overcurrent-protective devices in the phase conductors up to a rated current of 16 A. For higher rated values, the formula:

$$Z = \frac{25\ V}{6\ I_r}$$

can be used. I_r is the rated current of the overcurrent protective device.

The measurement of the protective earth conductor impedance should be performed with an ac current not less than 10 A and not exceeeding 25 A from a current source with a no-load potential not exceeding 6 V for a period of at least 5 s.

6.6.5 *Warning* — Measurement shall not be performed during patient occupancy.

6.7 Additional Safety Measures — The following safety measures serve as supplements to augment the installation systems given under **6.6** for protection against electric shock. Their utilization depends on the nature of the examinations or treatments performed and subject to the requirements of individual standards.

6.7.1 *P2 Supplementary Equipotential Bonding*

6.7.1.1 *Protective measure* — This protective measure is only applied additionally to P1. Its efficicacy can be further improved by combination with P4 or P5 (*see* **6.7.3** and **6.7.5**).

In order to minimize the effects of a touch voltage, all accessible conductive parts of the room are connected to the potential equalization system.

An equipotential bonding busbar shall be provided. It should be located near the protective earth conductor busbar (PE) and be connected to it. To the equipotential bonding busbar are connected:

a) all extraneous conductive parts, such as pipes for fresh water, heating, gases, vacuum and other parts with a conductive surface area larger than 0·02 m^2 (no linear dimension exceeding 200 mm) or smaller parts that can be grasped by hand.

b) an adequate number of potential equalization terminals, provided in each room for connection of flexible additional protective earth conductors of equipment. These connectors shall be provided with a suitable retaining device.

All equipotential conductors shall be of not less than 4 mm^2 copper or copper equivalent. Equipotential conductors shall be insulated, the insulation being coloured green/yellow.

6.7.1.2 *Restrictions* — The use of equipotential bonding must be restricted to one single room or to a group of functionally connected rooms. The interconnection conductors between potential equalization busbars of rooms shall be at least 16 mm^2 copper or copper equivalent.

6.7.1.3 *Initial testing of the room* — Inspection of the terminals of the busbar and at the equipment. Check that the marking, designation and destination of the conductors connected to the equipotential bonding bar are in accordance to the drawing of the installation system.

a) Inspection of the potential equalization connectors in the room.

b) Inspection of the flexible potential equalization conductors.

c) Measurement of the impedance of the potential equalization conductors. This impedance shall not exceed 0·2 Ω. The measurement of the impedance should be performed with an ac current not less than 10 A and not exceeding 25 A from a current source, no-load potential not exceeding 6 V rms for a period of at least 5 s.

WARNING — MEASUREMENT SHALL NOT BE PERFORMED DURING PATIENT OCCUPANCY.

6.7.2 *P3 Restriction of Touch Voltage in Room Equipped for Direct Cardiac Application*

6.7.2.1 This measure is applied additionally in rooms or at least in patient environment intended for direct cardiac applications. According to the high current sensitivity of the heart, no continuous ac voltage with frequency up to 1 kHz, exceeding 10 mV shall occur on a 1 000 Ω load between accessible conductive parts as well as extraneous conductive parts during normal conditions. This voltage is equivalent to the maximum allowable leakage current of 10 μA rms through the heart.

6.7.2.2 *Initial testing of the room* — Measurement of the potential differences between exposed conductive parts of the room.

A measuring instrument for testing such voltage differences is described in Appendix A. Because of the patient simulating internal resistance of 1 000 Ω, this measuring instrument shows μA, equal in the numerical value, at the same time.

To comply with the requirements, it might be necessary to apply one of the following methods:

a) Conductive parts may be additionally connected to a potential equalization bus bar by a conductor of sufficient cross-section in order to reduce voltage differences in the room (*see* P2). This can be supported by combination with P5.

b) Conductive parts may be insulated so that it is not possible to touch them unintentionally,

c) Extraneous conductive parts as pipes, etc, can be provided with insulated joints at those places where they leave or enter the room.

6.7.3 *P4 Application of Residual-Current Protective Devices*

6.7.3.1 Example is shown is Fig. 2.

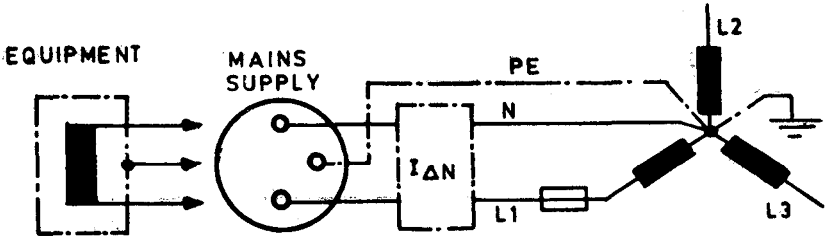


FIG. 2 APPLICATION OF RESIDUAL-CURRENT PROTECTIVE DEVICES

6.7.3.2 *Protective measure* — This measure is only applied additionally to P1.

By the use of residual-current protective devices $I\Delta_N$ in the mains supply before the mains socket outlets, the mains supply is quickly disconnected in case of an earth fault current, duration of touch voltages and consequently their influence on the heart can be reduced effectively. Without such a device the touch voltage lasts in case of a fault comparatively long, until the overcurrent protective device in the mains supply circuit disconnects the supply.

6.7.3.3 *Restriction* — The reduction of the risk of the occurrence of a touch voltage by residual-current operated protective devices not sufficient for direct cardiac applications. Thus it is necessary to apply additional provisions, for example, P1 and P2.

6.7.3.4 *Initial testing of the room* — Inspection of the residual current protective devices for rated residual operating current and maximum operating time.

The rated residual operating current should be above 0·03 A. The maximum operating time should not be longer than 40 ms at an operating test current of 0·25 A.

In the event of unknown switching characteristics of the protective device the value of the operating current of the protective device is determined by means of effecting an earth fault current through an adjustable resistor of sufficient capacity in series with a current meter. The current is slowly increased until the operating residual current is reached and determined.

After increasing the operating test current up to 0·25 A and suddenly switching on this presetted current, the operating time (disconnecting time) is determined in a second attempt.

CAUTION — MEASUREMENT MAY NOT BE PERFORMED DURING PATIENT OCCUPANCY.

6.7.4 *P5 Medical Isolated Transformer IT System*

Example is shown in Fig. 3. If the mains supply is isolated, the same electrical principles are valid.

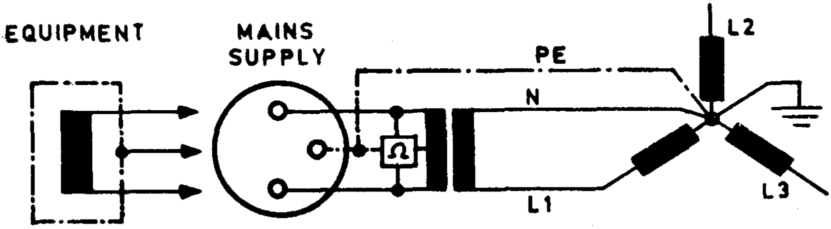


FIG. 3 MEDICAL ISOLATED TRANSFORMER (IT) SYSTEM

6.7.4.1 *Protective measure* — By use of a medical IT system, a symmetric power supply with a high impedance to earth is obtained.

An isolation monitoring device indicates degrading of the supply's impedance to earth below a preset limit visually and audibly. The acoustic alarm only can be temporarily cancelled.

The use of an isolated supply system for the supply may be desirable for different reasons :

a) the earth fault current in case of breakdown of basic insulation against earth in the equipment connected to it is reduced to a low value;

b) the leakage currents of equipment is reduced to a low value, where the medical IT system is approximately symmetrical to earth; and

c) the reliability of the power supply is increased by the prevention of automatic disconnection of the mains supply in case of high earth fault currents, as with P1.

In order to obtain the advantages of the isolated power supply system, it is necessary to:

i) keep the impedance to earth of the isolated supply system as high as possible;

ii) protect the isolating transformer from overload and short circuit;

The high impedance to earth may be achieved by:

1) restriction of the physical dimensions of the medical isolating transformer;
2) restriction of the system supplied by this transformer;
3) restriction of the number of medical electrical equipment connected to such a system; and
4) high internal impedance to earth of the [insulation monitoring device connected to such a circuit.

To protect the secondary of the IT system from overload and short-circuit, automatic overcurrent protective devices shall protect each individual socket outlet supplied by the isolated power system.

Only one item of equipment should be connected to each socket outlet to provide continuity of supply. Distribution boxes shall not be used.

The overcurrent protective devices shall be easily accessible and shall be marked clearly to indicate the protected circuit.

6.7.4.2 *Restriction* — This measure is restricted to the distribution system of one single room or a functionally connected group of rooms (for example, operation room with its service rooms).

If increase in reliability of the power supply is of major importance (for example, operating theatres, life supporting equipment), this provision needs additional safety measures as indicated in GE, E1 and E2.

6.7.4.3 *Initial testing of the room* — Inspection and measurement of the isolation impedance monitoring device.

By connection of an external conductor between one pole of a socket outlet of the isolated supply system and earth via an adjustable resistor in series with a current meter, earth fault resistances can be simulated and compared with the intended operating values of the alarm. Further, the maximum earth fault current of the isolated power system can be measured.

CAUTION — MEASUREMENT MAY NOT BE PERFORMED DURING PATIENT OCCUPANCY.

6.7.5 *P6 Medical Individual Electrical Separation*

6.7.5.1 *Protective measure* — In special used room, as hydrotherapy rooms, individual electrical separation of circuits as an extra safety measure may be used to prevent shock currents through contact with exposed conductive parts. These parts can be energized by a fault in the basic insulation.

The source of supply shall be a medical isolating transformer.

The voltage on the secondary circuit of the transformer shall not exceed 250 V.

To maintain the electrical separation of each equipment, live parts of the separated circuit shall not be connected at any point to any other circuit or earth.

Particular attention shall be paid to insulation of flexible cables and cords. These shall be visible throughout any part of their length where they are liable to mechanical damage.

Physical separation of all conductors from those of other circuits is necessary.

6.7.5.2 *Restriction* — This provision should only be used in rooms where the provisions P1 to P5 cannot give the necessary protection against shock currents.

6.7.5.3 *Initial testing* — The isolated supply transformer is tested according to **4.3.4**. Inspect that flexible cables and cords are installed according to the requirements above.

6.7.6 *Explosion and Fire Protection*

6.7.6.1 *Protective measure* — This method is applied in rooms, where the use of anaesthetics or skin cleaning and disinfection agents is intended, which in mixture with air or oxygen and nitrous oxide forms flammable atmosphere. The necessary special measures for avoiding explosions and fires include mainly the use of antistatic flooring and anaestheto-proof equipment.

6.7.6.2 *Initial testing of the room* — The resistance of an antistatic floor against earth shall not exceed 25 MΩ.

The measuring method is given in Appendix B.

Operating theatres and similar rooms which are not equipped with antistatic floor, should be so marked.

6.8 Standby Power Supply Systems

6.8.1 *Protective Measure* — This protective measure is supplied if, for medical reason, in the event of an interruption of the normal mains supply, the function of medical electrical equipment and of the lighting has to be ensured (life supporting and resuscitation equipment, operating lamps).

Within 15 seconds after a power supply failure, the safety supply system except operating lamp shall take over the electrical supply for at least 3 hours. The switch-over time for the operation lamp shall not be more than 0·5 seconds.

The safety supply system should preferably take over the supply of the whole room or of a group of rooms. As an alternative, individual group of equipment or single equipment may comprise internal safety supplies themselves (pacemakers, defibrillators) or they may be operated by hand (heart lung machine, respiration equipment).

6.8.2 *Measure to be Taken Prior to Putting into Operation* — If no safety supply is installed for the room or group of rooms, the operator shall have available equipment with an internal electrical power source of a sufficient capacity.

7. MARKING OF ROOMS

7.1 Marking of patient treatment areas to indicate the level of protection provided in the electrical installation and/or procedures which may or may not be undertaken, shall be done (for example, use of flammable agents prohibited, equipotential earthing areas, etc).

APPENDIX A

(*Clause* 6.7.2.2)

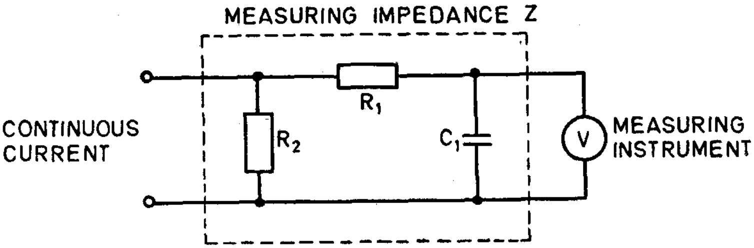
MEASURING DEVICE

A-1. The measuring device, such as voltmeter and microammeter shall have an impedance of approximately 1 000 Ω for dc, and for ac for frequencies up to and including 1 000 Hz.

A-2. For ac at frequencies 1 000 Hz, the response of the measuring device at a given frequency shall be inversely proportional to the response at 1 000 Hz by a factor equal to that frequency divided by 1 000. This response shall not be influenced appreciably by the impedance of the source to which the measuring device is connected.

The method presupposes that voltages at a frequency of 1 MHz or more are not present.

A-3. The measuring device can be made, for example, as shown in Fig. 4, which also shows the frequency characteristic. The deviation of the impedance frequency characteristics (*see* Fig. 5) from the theoretical characteristic shall be disregarded. The arrangement described makes it possible to use a direct indicating measuring instrument as the sole indicator.



$R_1 = 10\ \mathrm{k}\Omega \pm 5\%$
$R_2 = 1\ \mathrm{k}\Omega \pm 1\%$
$C_1 = 0{\cdot}015\ \mu F + 5\%$

FIG. 4 MEASURING DEVICE

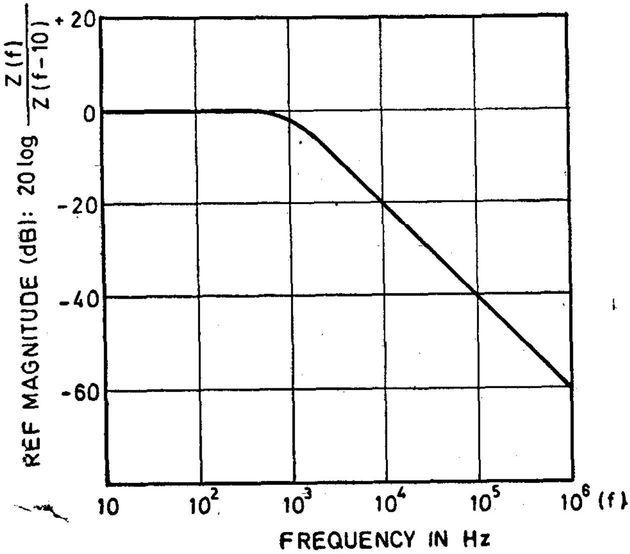


FIG. 5 FREQUENCY CHARACTERISTICS

A-4. The measuring instrument as shown in Fig. 1 shall be calibrated to indicate the true rms value of a full-wave rectified composite waveform having components from dc to 1 MHz with an indicating error not exceeding ±5 of the indicated value.

The frequency response from dc to 1 kHz shall be 3 dB or less.

For an analogue instrument the full-scale reading of the range use shall not be more than 30 mV.

APPENDIX B

(*Clause* 6.7.6.2)

MEASUREMENT OF THE RESISTANCE OF ANTISTATIC FLOORS

B-1. GENERAL

B-1.1 Measurement of the resistance of antistatic floors should be carried out under normal conditions, that is, without previously treating the antistatic floor in any way.

B-1.2 The contact areas between the antistatic floor and the test electrode should be dry and clean.

B-1.3 The resistance measuring device used should have a measuring voltage of above 500 V dc (megger).

B-1.4 For the measurement, one pole of the resistance measuring device should be connected to a protective conductor of the room concerned and the other pole should be connected to the test electrode.

B-1.5 The total contact area of the three conductive rubber pads to the floor should be 25 to 30 cm^2.

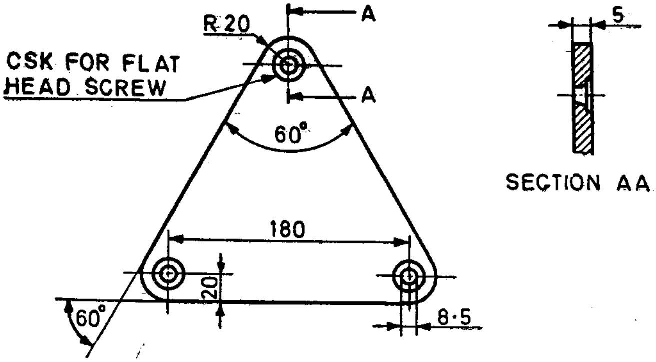
B-1.6 During the measurement, the test electrode should be loaded with a weight of not less than 50 kg.

B-1.7 The contact surface of the conductive rubber pads should be flat.

B-1.8 The resistance of a conductive rubber pad should not exceed 1 000 Ω measured between metal surface.

B-2. THE MEASURING ELECTRODE

B-2.1 The design and dimension of measuring electrode shall be as given in Fig. 6 to 8.



All dimensions in millimetres.

FIG. 6 ALUMINIUM ALLOY SHEET

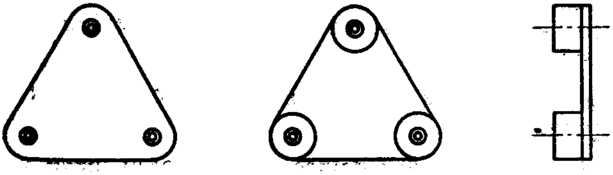
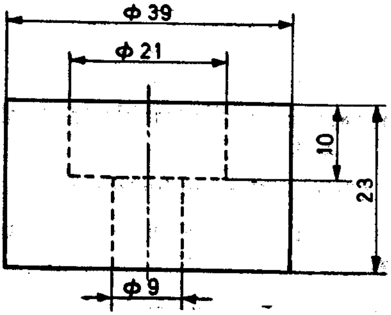


FIG. 7 TEST ELECTRODE FOR ANTISTATIC FLOORS



All dimensions in millimetres.

FIG. 8 CONDUCTIVE RUBBER PAD